

INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2004/017762

A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl⁷ A61K31/569, 9/10, 47/12, 47/14, 47/34, A61P27/02, 27/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl⁷ A61K31/569, 9/10, 47/12, 47/14, 47/34, A61P27/02, 27/16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
✓ Y	JP 2000-7569 A (Senju Pharmaceutical Co., Ltd.), 11 January, 2000 (11.01.00), Claims 1 to 4; Par. Nos. [0005], [0006] (Family: none)	1-6
✓ Y	JP 10-259132 A (Senju Pharmaceutical Co., Ltd.), 29 September, 1998 (29.09.98), Claims 1 to 3; Par. Nos. [0004], [0006], [0007], [0015] & WO 98/31343 A2 & EP 973501 A2	1-6

☒ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
05 January, 2005 (05.01.05)

Date of mailing of the international search report
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Name and mailing address of the ISA/
Japanese Patent Office

Authorized officer

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
✓ Y	WO 02/15878 A1 (Senju Pharmaceutical Co., Ltd.), 28 February, 2002 (28.02.02), Claims 1 to 29; page 10, line 27 to page 11, line 22 & EP 1312356 A1	1-6
✓ Y	JP 8-151332 A (Senju Pharmaceutical Co., Ltd.), 11 June, 1996 (11.06.96), Claims 1 to 6; Par. No. [0010] & EP 709099 A2 & CA 2159288 A	1-6
✓ Y	JP 10-316572 A (Senju Pharmaceutical Co., Ltd.), 02 December, 1998 (02.12.98), Claims 1 to 14; Par. Nos. [0004], [0006], [0008] & EP 868919 A2 & US 5916550 A	1-6

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International Searching Report

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V. Opinion under PCT Rule 43-2.1(a)(i) on Novelty, Inventive Step and Industrial Applicability, and the references supported thereof and explanation

1. Opinion

Novelty (N)	Claims	1 to 6	Yes
Inventive Step (IS)	Claims	1 to 6	No
Industrial Applicability (IA)	Claims	1 to 6	Yes

2. Cited references and Explanation

Reference 1: JP 2000-7569 A (Senju Pharmaceutical Co., Ltd.) 2000.01.11

Reference 2: JP 10-259132 A (Senju Pharmaceutical Co., Ltd.) 1998.09.29

Reference 3: WO 02/15878 A1 (Senju Pharmaceutical Co., Ltd.) 2002.02.28

Reference 4: JP 8-151332 A (Senju Pharmaceutical Co., Ltd.) 1996.06.11

Reference 5: JP 10-316572 A (Senju Pharmaceutical Co., Ltd.) 1998.12.02

(i) Inventions of Claims 1 to 6 do not have inventive steps from the references cited in the International Searching Report.

Reference 1 discloses a medicine for smell-disorder containing loteprednol etabonate in the form of a nasal-drop suspension (Claims 1 to 4). The reference also discloses para-oxybenzoic acid esters and sorbic acid etc as an additive, a nonionic surfactant as a suspending agent (0005), (0006).

Referring to References 2 and 3, in an aqueous suspension containing a hardly soluble drug such as loteprednol etabonate, an improvement of stability of the drug, preventing adhesion of the sedimented drug to the container and formation of blocking of the drug are known techniques. ((0003) in Ref. 2, page 2, lines 10-15 in Ref.3)

Referring to References 1 to 5, in an aqueous suspension of an eye-drop,

nasal-drop and ear-drop etc. containing hardly soluble drug such as loteprednol etabonate, sorbic acid, para-oxybenzoic acid ester and nonionic surfactant are known additives. ((0005) and (0006) in Ref.1, (0006) and (0007) in Ref.2, 4 line 27 on page 10 to line 22 of Ref.3, (0010) in Ref.4 and (0006) in Ref.5)

Therefore, in the inventions described in Ref.1, in order to improve the stability of the drug, and to prevent adhesion of the drug to the container, formation of aggregation of the drug, preparing the aqueous suspension containing loteprednol etabonate and compounding known additives such as sorbic acid, para-oxybenzoic acid ester and nonionic surfactant into the suspension is obvious to the skilled in the art and remarkable effect of the inventions by the compounding these additives can not be recognized.